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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/732,408	12/09/1996	JOHANNES REINMULLER	HUBR1099PFFM	7906

7590 09/30/2003  
FULBRIGHT AND JAWORSKI  
666 FIFTH AVE  
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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/30/2003

38

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/732,408

Applicant(s)

REINMULLER, JOHANNES *an*

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 129-181 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 129-181 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/5/03 has been entered.

### *Specification*

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the spaghetti-like strands being "solid" is not found in the disclosure. It is not clear what is meant by solid. Solid is understood as something rigid. This limitation appears to be unsupported and may need to be canceled.

### *Claim Objections*

Claims 158 and 159 are objected to under 37 CFR 1.75 as being duplicates of one another. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 156-159 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 156,157 recite the limitation "the hydrophobic surface" in line 2 of the claims. There is insufficient antecedent basis for this limitation in the claim. It is possible one claim should depend from claim 155.

Regarding claims 158,159, it is not clear as to what the scope of the claim is because the term "plastic" is broader than the limitations of claim 149 from which claims 158 and 159 depend. Silicone rubber is understood to be elastic, but some plastics are not resilient and permanently deformed. Thus it would appear that the claims contradict a prior limitation.

***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the implant "surrounded by an outer covering" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 129-132, 135-155, 160, 167-181 are rejected under 35 U.S.C. 102(e) as being anticipated by Henley (5534023). Fig. 1 shows a medical implant with a plurality of connected strands of material 14 and an outer covering 11. Henley discloses the covering is a silicone rubber, col. 4, lines 8-9. Henley also discloses the beads inside have extrudate chains that the Examiner is interpreting as "spaghetti-like strands" and is made of silicone, col. 4, lines 30-33. Regarding claim 155, the bead part must be hydrophobic in order to keep gas inside to maintain the density it was established for. With respect to claims 171-174, it can be construed that the strands are solid since they connect beads. Henley discloses the method of using such as implantation and the purpose of the design of the implant at a soft tissue site, col. 3, lines 60-65. Henley discloses lubricants to reduce friction, col. 6, lines 22-26.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 133, 134, 158, 159 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley '023 in view of Fisher (5496367). Henley '023 is explained as before. However, Henley does not disclose the use of plastic for the strand material.

Art Unit: 3738

Fisher discloses the use of plastic for structural material enclosed in an implant, col. 3, lines 18-22. It would have been obvious to one of ordinary skill in the art to substitute materials and use plastic as taught by Fisher in the implant of Henley such that it provides a little more rigidity.

Claims 156,157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley '023 in view of Perry et al. (5282857). Henley is explained supra. However, Henley does not disclose using fat or oil as a lubricant. Perry et al. teach that fats or oils in the form of glycerides are used in implants, col. 3, lines 1-4. It would have been obvious to one of ordinary skill in the art to use a fat or oil that wets a surface of the implant as taught by Perry with the implant of Henley in order to reduce friction and permit a more natural movement within the shell.

Claim 161,162 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henley '023 in view of Taylor (4657553). Henley is explained supra. However, Henley does not disclose the use of polysaccharides or polydimethylsiloxane as the implant material. Taylor teaches that polysaccharides are used in soft tissue implants, col. 1, lines 55-57. Taylor also teaches that polydimethylsiloxane is used in constructing medical implant material, col. 4, lines 37-44. It would have been obvious to one of ordinary skill in the art to use a polysaccharide or polydimethylsiloxane as the implant material as taught by Taylor for the implant of Henley because of the suitability of these materials in medical uses. Polysaccharides are not harmful if leakage does occur.

Claim 163 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henley '023 in view of Fisher '367 as applied to claim 158 above, and further in view of

Art Unit: 3738

Chapman (4348329). Henley as modified by Fisher is explained supra. However, Henley in view of Fisher do not disclose cuprophane as the implant material. Chapman teaches that polymers or "plastic" used in implants have coatings that are biocompatible, col. 6, lines 32-36, 49-54 and cuprophane is one material used (col. 13, lines 9, 12). It would have been obvious to one of ordinary skill in the art to use cuprophane as an implant material as taught by Chapman for the implant of Henley as modified by Fisher in order to reduce cell membrane damage.

Claims 164-166 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley '023 in view of Ledergerber (EP 322194). Henley is explained supra. However, Henley does not disclose a foam structure in the implant or X-ray medium incorporated in the implant. Ledergerber also discloses that foam can be used in the implant, col. 4, lines 8-18. Ledergerber additionally discloses that an x-ray contrast medium can be incorporated into the material, col. 12, lines 53-58. It would have been obvious to one of ordinary skill in the art to use a foam structure or a contrast medium in the implant as taught by Ledergerber with the implant of Henley such that it may be less dense as a result of using foam and is easily detected by imaging.

### *Response to Arguments*

Applicant's arguments with respect to claim 129-181 have been considered but are moot in view of the new ground(s) of rejection.

Art Unit: 3738

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino

TC 3700, AU 3738

A handwritten signature in black ink that reads "Brian E. Pellegrino". The signature is written in a cursive style with a large, stylized 'B' and 'P'.